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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,590	04/03/2002	Zhi Xian Chen	2577-124A	1775

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
09/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/009,590	CHEN ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,8-11,13,14,18-20,22,23,25,27 and 30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,8-11,13,14,18-20,22,23,25,27 and 30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-2, 4-5, 8-11, 13-14, 18-20, 22-23, 25, 27 and 30-36 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-2, 6-11, 13-14, 18-20, 23 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rangan et al (1993, US Patent 5,244,802) in view of Gawel et al (1990, Plant Cell, Tiss. Organ Devel. 23:201-204), and further in view of Price et al (1979, Plant 145:305-307) is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 103

4. Claims 1-2, 4-5, 8-11, 13-14, 18-20, 22-23, 25, 27 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rangan et al (1993, US Patent 5,244,802) in view of Gawel et al (1990, Plant Cell, Tiss. Organ Devel. 23:201-204) and further in view of Price et al (1979, Plant 145:305-307), and further in view of Tull et al (US Patent 6,242,257, filed May 1997). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 March 2008, as applied to claims 1-11, 13-14, 18-25 and 26-30. Applicant's arguments filed 9 June 2008 have been fully considered but they are not persuasive.

The claims are drawn to a method of producing a transgenic cotton plant comprising exposing petiole explants to Agrobacterium comprising a DNA encoding a selectable marker and an exogenous protein, culturing the explants to induce callus formation, selecting transformed callus, culturing the selected callus in suspension culture to induce embryoid formation, and regenerating the embryoid into a plant, wherein either glucose is the sole carbon source in all

media or wherein both glucose and sucrose are the carbon sources in the regenerating media.

Rangan et al teach culturing cotyledon or hypocotyl segments on MS media supplemented with 1-2 mg/l kinetin and 1-10 mg/l of the auxin NAA, with 20-30 g/l glucose as the only carbon source, to produce callus (column 8, lines 20-55; claims 1, 8-10). The callus is then grown in media supplemented with 0-1 mg/l cytokinetin and 1-10 mg/l of the auxin NAA to induce formation of embryogenic callus (column 8, line 55, to column 9, line 5). Embryogenic calli can be developed in suspension culture over about 5 to 36 days in media containing 1-10 mg/l NAA, with sucrose as the only carbon source; this media is also used for selection of transformed callus that expresses the exogenous gene and for formation of embryoids (column 9, line 46, to column 11, line 60; claim 17). Embryo germination occurs on a media containing 500 mg/l casein hydrolysate and about 1.2 g/l KNO_3 (column 9, lines 19-29; claim 1); casein hydrolysate is a nitrogen source containing both asparagine and glutamine. The resulting plantlets can grow on soil (claim 1).

Rangan et al disclose transformation of cotton plant segments with *Agrobacterium tumefaciens* harboring a vector comprising a selectable marker gene and an exogenous gene encoding a Bacillus thuringiensis toxin or resistance to glyphosate (Fig 11, 13). The plant cells were exposed to Agrobacterium in a medium with 2 mg/l NAA (column 14, lines 41-65), and were precultured prior to exposure to *Agrobacterium* (column 14, lines 10-15).

Rangan et al do not teach use of petioles as the explant material, use of 2,4-D as the auxin in the explant culturing step, use of a suspension culture in the embryogenic callus formation step, the lack of hormones in the exposing, selection, embryogenic callus formation, or embryoid formation media, use of 3.8 g/l KNO_3 and/or 500 mg/l asparagine and 1 g/l glutamine in the

germinating media, or use of glucose as the sole carbon source in all media or both glucose and sucrose as the carbon sources in the regenerating media. Rangan et al are silent as to the pH of the media they use.

Price et al teach culturing callus in a hormoneless suspension culture to induce formation of embryogenic callus and embryoids (pg 305, right column, paragraphs 2-5; entire pg 306).

Gawel et al teach use of cotton petioles as the explant material and culturing the explants in media containing 0.1 mg/l 2,4-D and 0.1 mg/l kinetin (pg 202, left column). Gawel et al also teaches culturing callus in suspension culture to induce formation of embryogenic callus and embryoids, and that liquid media was preferable (pg 202, right column, paragraph 2).

Tull et al teach use of glucose is the sole carbon source in all media (column 18, lines 36-53) and use of both glucose and sucrose are the carbon sources in the regenerating media (Table 4). Tull et al teach use of the carbon source at a concentration of 30 g/l (Tables 2-4)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the cotton transformation method taught by Rangan et al to use petioles as the explant material, to use 2,4-D as the auxin in the explant culturing step, to use a suspension culture in the embryogenic callus formation step, to use media lacking hormones in the exposing, selection, embryogenic callus formation, or embryoid formation steps, or to use 3.8 g/l KNO_3 and/or 500 mg/l asparagine and 1 g/l glutamine in the germinating media. One of ordinary skill in the art would have been motivated to use a suspension culture in the embryogenic callus formation step because plants Gawel et al teaches that suspension culture was preferable (pg 202, right column, paragraph 2). One of ordinary skill in the art would have been motivated to try hormoneless media because Price et al teaches that hormones are not necessary (pg 306, right

column, paragraph 2). One of ordinary skill in the art would have been motivated to use petioles as the explant material and 2,4-D as the auxin because of Gawel's success with them. One of skill in the art would have tried different concentrations of the hormones in the selection step , including 0.0.5 mg/l 2,4-D in the course of optimization of experimental parameters. One of ordinary skill in the art would have been motivated to try 3.8 g/l KNO_3 and/or 500 mg/l asparagine and 1 g/l glutamine in the germinating media in the course of optimization of experimental parameters.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of cotton transformation as taught by Rangan et al in view of Gawel et al and further in view of Price et al, to use glucose as the sole carbon source in all media or use both glucose and sucrose as the carbon sources in the regenerating media as described in Tull et al. One of ordinary skill in the art would have been motivated to do so because Tull et al teach that use of glucose as the sole carbon source reduces the necessity of frequent subculture (column 18, lines 48-53), and because young plants can be obtained on media containing both glucose and sucrose (claim 6). One of skill in the art would have tried different concentrations of sucrose and/or glucose, including 10 g/l of each of glucose and sucrose in the regenerating media in the course of optimization of the protocol.

If the media used in the culturing, selecting, developing and geminating steps in the above references are not at a pH of 6.2 to 7.0 or 6.5 and the media in the rooting steps not at a pH of 7.0, then it would be obvious to one of skill in the art to try these pHs, as they are close to cellular pHs.

Applicant urges that Rangan does not disclose the use of 1.2 g/l KNO_3, but uses 1.2 g/l NH_4NO_3 ; the amount of KNO_3 is greater than claimed in the instant application (response pg 10).

This is not found persuasive because Rangan uses KNO_3 in the callus growth and maintenance medium (column 5, line 65) and in the embryo germination medium ((column 6, line 60). The amounts given are for stock solutions - note that it says that 40 ml/l of the 25.275 g/l stock is used in the final solution (column 6, lines 60-63).

Applicant urges that Rangan grew the suspension cultures for 3-4 weeks, filtered and further cultures for 3-4 weeks and uses the suspension culture to proliferate embryogenic callus not to induce embryogenic calli (response pg 10).

Rangan indicates that every 3-4 weeks the suspension culture must be filtered to remove embryogenic callus (column 9, lines 62-65); three weeks is "less than about 20 days". Nonembrygenic callus used a starting material. Rangan consistently refers to nonembrygenic callus as "callus" and embryogenic callus as "embryogenic callus".

Applicant urges that Rangan teaches sucrose as a carbon source for the initiation of embryogenic callus; there is no teaching or suggestion in Rangan to use the specific steps as set forth in the present claims (response pg 10-11).

This is not found persuasive because the rejection is based on a combination of references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant urges that Gawel does not describe a method that includes transformation, and uses hormones (response pg 11-12).

This is not found persuasive because the rejection is based on a combination of references. Gawel is cited for its teaching of cotton petioles as the explant material, and that for culturing callus to induce formation of embryogenic callus and embryoids suspension culture is preferable.

Applicant urges that Price only related to somatic embryogensis and does not describe a method for transformation and that embryos fail to perform when transferred to Stewart and Hsu medium (response pg 12).

This is not found persuasive because the rejection is based on a combination of references. Price is cited for its teaching that hormones are not necessary for formation of embryoids. The reference was not used any teaching of germinating embryos in Stewart and Hsu medium.

Applicant urges that they have described two key features, one being transforming calli to liquid MMS2 medium and the second being use of asp and/or glu; both of these key features are not described or suggest in the art (response pg 12-13).

This is not found persuasive. Use of asp and/or glu as the nitrogen source is a known step in the art; see Price et al, pg 306, left column, paragraph 3. Applicant is not claiming use of MMS2 medium and has not pointed out how this medium differs form any of the media used in the cited references.

Applicant urges that because of the well-known issue of plant cell viability following Agrobacterium transformation, they do not believe that a skill artisan would reasonable expect that the simple application of somatic embryogensis techniques could be combined with transformation protocols as in this rejection; the art cited shows unpredictability. For example, Price shows 2iP and NAA are required to produce somatic embryoids (response pg 13-14).

This is not found persuasive. Price does not show that NAA and 2iP were necessary. Prices shows that the auxin 2, 4 D was NOT necessary (pg 306, left column, paragraph 5); t other auxins, like NAA, were not present. Price specially did not teach whether 2iP or other cytokinins were required, but suggesting testing if that is the case (paragraph spanning the columns on pg 306).

Applicant urges that Tull relates to organogenesis, which is not embryogensis, and uses hormones (response pg 14-15).

This is not found persuasive. Tull is cited for its use of medium containing glucose as the sole carbon source in tissue culture of cotton. One of skill in the art would try what worked in the cotton tissue culture art in methods of making transgenic cotton plants. One of skill in the art would try using both glucose and sucrose in the medium for growing the young transgenic plant because Price indicates that either is fine for this purpose.

Applicant has not indicated why it would not be obvious to one of skill in the art to combine these established methods in the art to arrive at the claimed invention. The well-known issue of plant cell viability following Agrobacterium transformation would motivate one of skill in the art to try different known steps to overcome any obstacles in cotton transformation via Agrobacterium.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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September 17, 2008

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638